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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,612	11/13/2001	Alessandro Massimo Gianni	GIANNI=1	5788

1444 7590 06/02/2003

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/869,612

Applicant(s)

GIANNI, ALESSANDRO MASSIMO

Examiner

Fozia M Hamud

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### ***Election/Restrictions***

1. This application is a 371 of PCT/EP99/10470. For applications filed under 371, PCT rules for lack of unity apply.

2. This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept. Under PCT Rule 13.1 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required:

I. Claims 1, 3-13, 18-30, 32-36, 43-55, drawn to a method of preparation of a population of circulating cells by administering to a donor a composition comprising growth hormone.

II. Claims 2, 4-13, 17-26, 31, 55, drawn to a method of preparation of a population of circulating cells by administering to a donor a composition comprising growth hormone and G-CSF.

III. Claims 14-16, 18-30, 32-55, drawn to a method of preparation of a population of circulating cells by administering to a donor a composition comprising growth hormone and (a hematopoietic growth factor or a chemokine).

IV. Claims 14-16, 18-30, 32-55, drawn to a method of preparation of a population of circulating cells by administering to a donor a composition comprising growth hormone and monoclonal antibodies.

3. Claims 29-55, which recite "use of human growth hormone to prepare medicament.....", are interpreted as being drawn to a composition comprising growth hormone.

Pursuant to 37 C.F.R. 1.475(d), this Authority considers that the main invention in the instant application comprises the first-recited method, namely a method of preparation of a population of circulating cells by administering to a donor a composition comprising growth hormone and the first recited product, namely, a composition comprising growth hormone. Further, pursuant to 37 C.F.R. 1.475(b)-(d), the ISA/US considers that the materially dissimilar methods of group II-IV, using products that are

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different than the product used in Group I, and thus, do not correspond to the main invention. This Authority therefore considers that the several inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.

**Species Election:**

4. Claims 16, and 35, recite several compounds that the composition of claims 1-3 should further comprise or should be administered with the composition of claims 1-3.

The species recited in claims 16 and 35, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited cytokines and chemokines lack the same or corresponding special technical features, because they have different structures and functions.

Applicant is required, in reply to this action, to elect a single cytokine or chemokine (depending on which species is elected) to which claims 16 and 35 are restricted to. The reply must also identify the claims readable on the elected disease, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
May 23, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800